INTRODUCTION

Medtronic’s commitment to quality has long been stated as part of the Medtronic Mission. We will *strive without reserve for the greatest possible reliability and quality*. The annual Medtronic Product Performance Report (PPR) reflects that commitment. Through this sharing of information, we can enable physicians to best leverage state-of-the-art therapy delivery and also understand the performance of our devices to best manage patients. Together, we can further patient safety and improve lives.

METHODS

- Medtronic uses a prospective, long-term, multi-center registry to monitor the performance of certain products at selected centers titled the Product Surveillance Registry (PSR).
- Medtronic also incorporates the findings of Returned Product Analysis (RPA) for devices followed in the registry that are returned to Medtronic.
- Patients at each center who provide informed consent are enrolled in the registry. Patients are followed prospectively for events related to the device, procedure, and/or therapy.
- Participating investigators provide event descriptions, patient symptoms, and patient outcomes. Any detection methods used to determine patient or device outcomes are also obtained.

EVENT CATEGORIZATION

Events collected through the registry are collapsed into two categories:

- **Product performance** — event possibly due to a device-related issue.
- **Non-product performance** — any undesirable patient symptom, illness, or other medical event that appears or worsens during the clinical study that possibly resulted from or was related to the implant procedure, therapy, or delivery of therapy, and cannot be classified as a product performance event.

DEVICE SURVIVAL ESTIMATES

Note that cumulative device survival — not patient survival — estimates are presented throughout this summary.

- Figures show the percentage of implanted devices that remain free from product performance-related events at various time points.
- Example: a device survival probability of 90% indicates that through the stated follow-up time period, the device had a 10% risk of incurring a product performance event since the time of implant.
- Estimates represent device survival where at least 20 total devices are still being followed for at least 6 months.

PATIENT ENROLLMENT

- 20 centers enrolled 969 total sacral neuromodulation patients in the registry through October 31, 2017.
- 41.5% of patients were implanted for the treatment of urinary urge incontinence.
- 31.8% of patients were implanted for the treatment of urgency-frequency.
- 12.1% of patients were implanted for the treatment of urinary retention.
- 4.7% of patients were implanted for the treatment of fecal incontinence.
- 8.1% of patients were implanted for the treatment of some other indication.
- 1.8% of patients were implanted for the treatment of indications not specified in the database at the time of the data cut-off.
<table>
<thead>
<tr>
<th>Model Number/ Product Name</th>
<th>Devices Enrolled</th>
<th>Device Events</th>
<th>Cumulative Months of Follow-up</th>
<th>1 yr</th>
<th>2 yrs</th>
<th>3 yrs</th>
<th>4 yrs</th>
<th>5 yrs</th>
<th>6 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Neurostimulators†</strong></td>
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<td></td>
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<tr>
<td>InterStim™</td>
<td>101</td>
<td>2</td>
<td>2,816</td>
<td>98.9%</td>
<td>98.9%</td>
<td>98.9%</td>
<td>96.0%</td>
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<tr>
<td>InterStim™ II</td>
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<td>9</td>
<td>14,252</td>
<td>99.6%</td>
<td>98.5%</td>
<td>97.4%</td>
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<tr>
<td><strong>Leads‡</strong></td>
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<tr>
<td>Model 3889</td>
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<td>60</td>
<td>14,163</td>
<td>95.3%</td>
<td>90.4%</td>
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<td>94.0%</td>
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<tr>
<td><strong>Extension‡</strong></td>
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<tr>
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<td>98.3%</td>
<td>98.3%</td>
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</tr>
</tbody>
</table>

* Table shows the percentage of implanted devices that remain free from product performance-related events at various time points.
† There were 74 lead-related product performance events reported to the registry, but only 64 events included in this summary table. The remaining events occurred in a lead model for which no device survival curve is presented due to an insufficient number of enrolled devices (i.e., Model 3080) (n=2) or were subsequent events that did not affect the device survival estimates.
‡ There were 2 extension-related product performance events reported to the registry, but only 1 event included in this summary table. The remaining event was a subsequent event that did not affect the device survival estimates.

If you have suggestions, inquiries, or specific problems related to our products or this information, contact:

Medtronic
U.S. Technical Services Department
Phone: (800) 707-0933
Fax: (763) 367-1406
Indications for Use:

Sacral Neuromodulation delivered by the InterStim™ system for Urinary Control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

The following Warning applies only to Sacral Neuromodulation for Urinary Control:

**Warning:** This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

Sacral Neuromodulation delivered by the InterStim™ system for Bowel Control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

**Contraindications for Urinary Control and for Bowel Control:** Diathermy. Patients who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.

**Warnings/Precautions/Adverse Events:**

For Urinary Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for patients with neurological disease origins.

For Bowel Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 18; or for patients with progressive, systemic neurological diseases.

For Urinary Control and for Bowel Control: The system may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors/ screening devices. Adverse events include pain at the implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations, including jolting or shock sensations. Patients should be assessed preoperatively for the risk of increased bleeding. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic’s website at www.medtronic.com. Product technical manual must be reviewed prior to use for detailed disclosure.

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